

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

4

Docket No.: 61843USN(51035)

REMARKS

Claims 1 through 5 and 12 through 14 are pending in this application. By this amendment, claims 1, 4, 5, and 11 through 14 are currently amended. Claims 6 through 10 are canceled by this amendment.

Amendment of any claim herein is not to be construed as acquiescence to any of the rejections/objections set forth in the instant Office Action, and was done to expedite prosecution of the application. Applicants make these amendments without prejudice to pursuing the original subject matter of this application in a later filed application claiming benefit of the instant application, including without prejudice to any determination of equivalents of the claimed subject matter. Support for these amendments appears throughout the specification and claims as filed. No new matter is introduced by these amendments.

Rejection under 35 U.S.C. 112, second paragraph

Claims 1 through 5 and 12 through 14 are rejected as failing to comply with the written description requirement. Applicants traverse.

Claim 1 is rejected for being vague and indefinite as to whether the invention is a method of making an organic food supplement for livestock or a method of orally administering or "delivering" an organic food supplement to livestock. Claim 1 is also rejected for being vague and indefinite for the phrase "delivering the hops for oral ingestion" because it is unclear to whom the hops acids are delivered. Applicants amend claim 1 to a "method of preparing an organic food supplement" and "mixing the hops acids for oral ingestion with a livestock feed." Support for these amendments appear throughout the specification as filed.

DC_234040_1

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

5

Docket No.: 61843USN(51035)

Claim 1 is rejected for being vague and indefinite for the phrase "to inhibit certain types of undesirable bacteria commonly found in the digestive system of livestock." Applicants amend claim 1 to remove the phrase "certain types" and have added various bacteria and protozoa desirably inhibited by the claimed invention.

Applicants amend claim 1 to reflect proper antecedent basis.

Claims 1, 2, 6, 10, and 12 through 14 are rejected for clarity as to the identification of the ingredient "hop." The Office Action states the Latin genus-species name of each ingredient should accompany non-technical nomenclature. Applicants amend the claims to recite "*Humulus lupulus* (hop)" in the independent claims. This definition is present in the specification in column 2, line 26.

Claim 4 is amended to correct a typographical error.

The Applicants amend claim 5 to reflect proper antecedent basis.

Applicants amend claim 12 to clarify the subject to which the claim is directed and to reflect proper antecedent basis.

Claim 13 is rejected for being vague and indefinite for the phrase "inhibiting certain types of undesirable bacteria commonly found in the digestive system of livestock." Claim 13 is amended to remove the phrase "certain types" and have added various bacteria and protozoa desirably inhibited by the claimed invention.

Applicants replace the first occurrence of ppm in each claim with "parts per million (ppm)."

DC_234040_1

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

6

Docket No.: 61843USN(51035)

Based on the foregoing, Applicants respectfully request withdrawal of the rejection.

Claim Objections

Claims 5, 12 and 14 are objected to under 37 C.F.R. 1.75(e) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants amend claims 5 and 12 to reflect proper dependent form. Based on the foregoing, Applicants respectfully request withdrawal of the objection.

Rejection under U.S.C. 102(b)

Claims 1 through 5 and 12 through 14 are rejected as anticipated by Heinemann (B), as evidenced by the teachings of Kurhts (C), Owades (D) and Murtaugh et al. (E). Applicants traverse.

It is asserted in the Action that Heinemann teaches substituting hulled barley steeped in an infusion of hop flowers and then drying. (Heinemann p. 1, lines 59 - 63.) Heinemann teaches the purpose of steeping the hulled barley in hops flowers is because the drink prepared from the barley would otherwise be tasteless, and the hop flowers provide a bitter taste. (Heinemann p.1 lines 19 - 22 and lines 35 - 37.)

It is well established that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Heinemann does not teach each and every element of the claimed subject matter.

DC_234040_1

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

7

Docket No.: 61843USN(51035)

As admitted in the Office Action, Heinemann does not teach the use of hop acids.

(Office Action p. 9.) The claimed invention utilizes a mixture of alpha and beta acids and their corresponding salts to achieve the method of preparing the organic food supplement to inhibit undesirable bacteria in the digestive systems of livestock. Nothing in Heinemann suggests the use of hop acids as a feed supplement to inhibit undesirable bacteria in the digestive system of livestock.

Heinemann describes methods of making a coffee-substitute using barley that is hulled and roasted and steeping it with hops flowers. This is done to add bitterness to the barley such that the resulting beverage has a flavor, preferentially one akin to coffee. It is not at all clear whether the "hops flowers" used in Heinemann are literally the flower portion or the cone portion of the hops. Furthermore, it is not at all clear whether it is hops acids or other components of the hops flowers that provide the desired bitterness characteristic to the steeped barley; thus making it unclear what amount, if any, of hop acid is present in the Heinemann coffee-substitute. Even further, because the applications are so different (Heinemann adding bitterness to the coffee substitute, which is antithetical to Applicants' goal of producing a feed that is palatable rather than bitter to livestock) it is unclear what amount, if any, of hop acid is present.

The secondary references additionally do not compensate for the deficiencies of Heinemann. Kuhrt teaches a method for producing a sustained-release powder made from high viscosity liquids with hops extracts as a possible ingredient. Owades teaches a method of preventing sunburn to human skin by using a sunscreen containing hops extracts. Murtaugh teaches a method of making hop extract and a hopped beverage. Each of these references deals with hop extracts, but provide no indication that they relate to the Heinemann process using

DC_234040_1

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

8

Docket No.: 61843USN(51035)

flowers or provide any indication that Heinemann must necessarily have any particular level of hops acid present, if any at all. These references, alone or in combination, do not teach the combination of the acids and their salts to inhibit the bacteria and protozoa in the digestive systems of livestock as in the claimed invention. As such, Applicants submit that the cited references (i.e., Kurhts (C), Owades (D), and Murtaugh et al. (E)) do not provide any clear evidence that the Heinemann coffee-substitute has any particular levels of hop acids, or even any hop acids at all, that are useful for inhibiting the recited bacteria in the digestive system of livestock (which level is also a claim limitation).

It is also established that "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 f.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). In relying on a theory of inherency, it must be established that the missing characteristic necessarily flows from the prior art teachings. See, MPEP 2112(IV). Heinemann does not teach the use of hop acids and the cited art (i.e., Kurhts (C), Owades (D), and Murtaugh et al. (E)) does not necessarily establish with any degree of certainty whatsoever that the Heinemann coffee-substitute possesses every element of Applicants' claimed subject matter.

Based on the foregoing, Applicants submit that all elements of the claimed subject matter are not described in the Heinemann process nor do any of the other cited references describe

DC_234040_1

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

9

Docket No.: 61843USN(51035)

how the claimed limitations must necessarily be present in Heinemann. Applicants therefore respectfully request the rejection be withdrawn.

Rejection under 35 U.S.C. 102(b)

Claims 1 through 5 and 12 through 14 are rejected as being anticipated by Feil (N), as evidenced by Kurhts (C), Owades (D), and Murtaugh et al. (E).

Feil teaches a disinfectant for use as an insect repellent for protection of plants and flowers consisting of barley, malt, hops, vitamin B and alcohol. (Feil abstract.) As stated in the Action, Feil does not teach that the reference composition comprises hop acids. Feil also does not teach the use of hop acids, the properties of hop acids, or the method of preparing a food supplement to inhibit undesirable bacteria in the digestive system of livestock. The secondary references do not supplement the deficiencies of Feil because nothing in the references, as discussed above, teach or suggest the combination of the acids and their salts to inhibit undesirable bacteria in the digestive systems of livestock as in the claimed invention, nor is there any teaching of the desired levels of such hop acids. These references, alone or in combination, do not teach the combination of the acids and their salts to inhibit the bacteria and protozoa in the digestive systems of livestock as in the claimed invention.

The reasoning delineated above for Heinemann also apply to Feil. Applicants submit that the cited references (i.e., Kurhts (C), Owades (D), and Murtaugh et al. (E)) do not provide any clear evidence that the Feil insect repellent composition has any particular levels of hop acids, or even any hop acids at all, that are useful for inhibiting the recited bacteria in the digestive system of livestock (which level is also a claim limitation). Applicants respectfully request the rejection be withdrawn.

DC_234040_1

Application No. National Phase of US03/30304 10
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

Docket No.: 61843USN(51035)

Rejection under 35 U.S.C. 102(b)

Claims 1, 2, 5, and 12 through 14 are rejected as being anticipated by Papadopoulou et al.

(U). Applicants traverse.

Papadopoulou provides no teaching of an animal feed. Rather, Papadopoulou discusses the control of selected microorganisms during the malting process. The reference teaches the addition of 1ppm of α -acid during steeping or at cast, eliminated *Chromobacterium*, *Clavibacterium*, and fungi. Hop β - acid was used at 1ppm and 10ppm barley prior to kilning. Use of 1ppm prior to kilning reduced fungal levels to zero but did not affect other microorganisms.

Papadopoulou relates to malt preparation, and more particularly relates to malt for use in brewing processes. Malt is distinct and distinguishable from animal feed compositions (i.e., starting grain) as it is subjected to processing that involves a number of transformations including for example, germination, enzyme formation, drying, root removal, etc. Further, this reference does not teach the combination of the acids and their salts to inhibit the bacteria and protozoa in the digestive systems of livestock as in the claimed invention, nor provides any teaching of the presence, or desired levels, of hops acids in animal feed for such purpose. The reasoning delineated above for Heinemann also applies to Papadopoulou. Applicants submit that Papadopoulou does not provide animal feed compositions, nor animal feed compositions having any particular levels of hop acids, or even any hop acids at all, that are useful for inhibiting the recited bacteria in the digestive system of livestock (which level is also a claim limitation). Based on the foregoing, Applicants submit that Papadopoulou does not teach each and every element of the claimed subject matter and respectfully request the rejection be withdrawn.

DC_234040_1

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

11

Docket No.: 61843USN(51035)

Rejection under 35 U.S.C. 102(b)

Claims 1 through 5 and 12 through 14 are rejected as being anticipated by Egorova (BG, RU 2075298) as evidenced by the teachings of Kurhts (C), Owades (D), Murtaugh et al. (E) and Mannering et al. (V).

Egorova teaches the use of hop grains in animal feed. The mixture contains 0.2 (wt %) hops grains. Egorova does not teach the use of hop acids, nor does Egorova teach their use in inhibiting the specifically recited bacteria in Applicants' claims. The Office Action relies on the secondary references to teach that acids are inherent to hops. The secondary references do not compensate for the deficiencies of Egorova. The above discussion of Kurhts, Owades, and Murtaugh is incorporated herein. Mannering does not teach the bacteria inhibited in the claimed invention. Each of these references deals with hop extracts, but provide no indication that they relate to the Egorova formulation or provide any indication that Egorova must necessarily have any particular level of hops acid present, if any at all. These references, alone or in combination, do not teach the combination of the acids and their salts to inhibit the bacteria and protozoa in the digestive systems of livestock as in the claimed invention. Applicants therefore respectfully request the rejection be withdrawn.

Rejection under 35 U.S.C. 102(b)

Claims 1 through 5 and 12 through 14 are rejected as being anticipated by Thompson et al. (F), as evidenced by the teachings of Kurhts (C), Owades (D), Murtaugh et al. (E), Mannering et al. (V), and Miller et al. (BG GB 2072657).

DC_234040_1

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

12

Docket No.: 61843USN(51035)

Thompson teaches a method of preventing liver abscesses in the feeding of cattle on high concentrate rations containing more than 75 percent corn, by incorporating up to 20 percent by weight dried brewers grains in the ration. Thompson does not teach the use of hops acids. Thompson teaches incorporating dried brewers grain into animal feed. Thompson defines dried brewers grain as "the dried residue of barley malt alone or in mixture with other cereal grain or grain products resulting from the manufacture of wort and may contain pulverized spent hops in the amount not to exceed 3 percent evenly distributed." (Thompson, column 2, lines 32 - 36.) It is unclear whether Thompson contains any hops, and if so, what actual level of hops, and is even more speculative as to levels of hops acids present, if any.

The secondary references do not compensate for the deficiencies of Thompson. The above discussion of Kuhrts, Owades, Murtaugh, and Mannering is incorporated herein. Muller (Muller) (GB 2072657) teaches a process for obtaining hulupulones from lupulones. It is asserted in the Action that Muller teaches that lupulones or beta-acids are inherent to spent hops. Applicants disagree. Muller states that lupulones are discarded in their process with the spent hops, not that the spent hops necessarily have beta-acids in them. In fact, depending on the processing involved, spent hops may not have beta-acids present. In many instances the beta acids are in fact extracted away from the spent hops in order to secure them; thus leaving spent hops devoid of beta acids. A closer reading of the Muller example does not indicate that the spent hops necessarily has beta acids present. Based on the foregoing, Applicants submit that all elements of the claimed subject matter are not described in Thompson process nor do any of the other cited references describe how the claimed limitations must necessarily be present in Thompson. Applicants therefore respectfully request the rejection be withdrawn.

Rejection under 35 U.S.C. 103(a)

DC_234040_1

Application No. National Phase of US03/30304 13
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

Docket No.: 61843USN(51035)

Claims 1 through 5 and 12 through 14 are rejected as anticipated or in the alternative, as obvious over Thompson et al (F), in view of Schmalreck et al (X), Lewis et al. (W), Chin et al. (U1), Haas et al. (AC, U.S. Patent No. 6,432,317 B1), Barney et al. (G), Nutter et al. (I), and Nutter et al. (U.S. Patent No. 6,313,178 B1) and Johnson et al. (G), and further in view of Mannering et al. (V) and Miller et al (BG, GB 2073657).

Thompson teaches incorporating dried brewers grain into animal feed as described above. Thompson does not teach that brewers grain or that the resulting animal feed composition necessarily comprises hop acids, nor provides any indication of what levels of hops acids are beneficial for inhibiting the bacteria specifically recited in Applicants' claims. Thompson does not teach the antibacterial properties of the hop acids.

The Office Action cites to ten references to support the rejection. Clearly Thompson does not teach or suggest the claimed invention. The secondary references cited do not compensate for the deficiencies of Thompson. None of the references, alone or in combination teach the combination of the acids, their levels beneficial for inhibiting the bacteria specifically recited in Applicants' claims, or their salts to inhibit the bacteria and protozoa in the digestive systems of livestock as in the claimed invention. Applicants respectfully request the rejection be withdrawn.

Double Patenting Rejections

Claims 6 through 11 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 through 6 of U.S. Patent No. 7,090,873 B2 (A). Applicants cancel claims 6 through 11 of the present application.

DC_234040_1

JAN. 28. 2008 9:26PM

EAP&D 617 227 4420

JAN 28 2008

NO. 4679 P. 17

Application No. National Phase of US03/30304
Amendment dated January 27, 2008
Reply to Office Action of July 26, 2007

14

Docket No.: 61843USN(51035)

Claims 1 through 14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 through 14 of copending U.S. Application No. 11/499,502. It is submitted that all prior rejections are properly withdrawn and therefore the instant provisional rejection should also be withdrawn according to Section 804 of the Manual of Patent Examining Procedure.

In view of the above amendment, Applicants believe the pending application is in condition for allowance. Should any of the claims not be found to be allowable, the Examiner is requested to telephone Applicants' representative at the number below. Applicants thank the Examiner in advance for this courtesy.

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 51035-61843.

Dated: January 28, 2008

Respectfully submitted,

By 

Jeffrey D. Hsi

Registration No.: 40,024

EDWARDS ANGELL PALMER & DODGE
LLP

P.O. Box 55874

Boston, Massachusetts 02205

(617) 517-5569

Attorneys/Agents For Applicant